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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,449	02/24/2004	Tracee Eidenschink	15305.0019US01	8514

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EXAMINER	
NGUYEN, VI X	

ART UNIT	PAPER NUMBER
3734	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,449	EIDENSCHINK, TRACEE	
	Examiner	Art Unit	
	Victor X. Nguyen	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48 and 51-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-48 and 51-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The request filed on 08/29/2008 for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/785,449 is acceptable and a RCE has been established. An action on the RCE follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 60-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claim 60, the disclosure does not describe "one or more electroactive polymers, wherein the one or more electroactive polymers are configured to expand when activated by an electric current". Clarification is requested.

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 28-30,32-33, 35-40, 56,58 and 59, are rejected under 35 U.S.C. 102(e) as being anticipated by Gumm (US-20030055483). Gumm discloses a catheter assembly

comprising: Regarding claim l, a catheter shaft (14), the catheter shaft having a length and an outer surface; a balloon (28), the balloon comprising a proximal balloon waist(30), a distal balloon waist (32) and a body portion (28) there between, the balloon having an expanded state and a unexpanded state, in the expanded state the body portion having an expanded diameter and in the unexpanded state the body portion having an unexpanded diameter that is less than the expanded diameter (inherent); and a proximal collar (24) and a distal collar (26), the proximal collar fixed to the catheter shaft 14 and the distal collar fixed to the catheter shaft (para.O040), each collar having a nonactivated state and an activated state, in the nonactivated state the distal balloon waist being rotatable about the distal collar and the proximal balloon waist being rotatable about the proximal collar (para.0041), in the activated state the proximal collar being expanded to sealingly engage the proximal balloon waist and the distal collar being expanded to sealingly engage the distal balloon waist (para.0041,0045).

Regarding claim 28, a distal hub (22), the distal hub fixedly engaged to the catheter shaft distal of the distal collar.

Regarding claim 29, a proximal hub (20), the proximal hub fixedly engaged to the catheter shaft proximal of the proximal collar.

Regarding claim 30, a secondary guidewire housing (60), the secondary guidewire housing comprising a substantially tubular member engaged to the balloon (fig. 2), the secondary guidewire housing defining a secondary guidewire lumen through which a secondary guidewire (62) may be slidingly positioned.

Regarding claims 32, 33, and 35, figure 4 discloses the secondary housing

guidewire integral and engaged to the balloon and extending from a proximal end to an intermediate region of the balloon.

Regarding claim 36, the secondary guidewire (62) has a length at least as long as the balloon body (fig. 2)

Regarding claim 37, a balloon expandable stent (50), the stent being expandable from an unexpanded configuration to and expanded configuration, in the unexpanded configuration the stentt being disposed about at least a portion of the balloon body (para.0043).

Regarding claim 38, at least a proximal portion of the stent (50) overlays at least a portion of the secondary guidewire housing (fig. 2).

Regarding claim 39, the stent (50) comprises a plurality of interconnected members, wherein adjacent members define openings there between, one of the openings being a secondary'opening (64) through which the secondary guidewire (62) radially extends (fig. 2).

Regarding claim 40, a distal end of the secondary guidewire housing (60) extends radially through the secondary opening (64).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2,5,16-21 ,31 ,47-48 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (US-20030055483) in view of Gerberding et al. (US-6315790).

Gumm discloses the invention substantially as disclosed above, but fails to disclose marker bands.

Gerberding teaches marker bands (30), wherein at least one marker band is at least partially radiopaque and are detectable by X-ray (co 1.4, line 9-11).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the catheter disclosed by Gumm to include marker bands as taught by Gerberding.

Regarding claims 2-5, 20-21, 47-48 and 57, it is old and well known in the art of the catheter assembly having the collars that is exposure to an electric current (see for-example, US Pat 6,432,064, fig. 6, element 44 and US Pat 5,425,703, fig. 3, element 38).

Regarding claims 6-11,13-14,19,22-27,31, 46, it is old and well known in the art for the balloon and the secondary guidewire housing to be constructed of at least one member of the group consisting of: Pebax, Nylon, PET, polyester, polyolefin copolymer and any combination thereof. See for example, US patent #s 4838859, 4906244, 4950239, 5290306, and 2002/0146557.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (US-20030055483) in view of Marton (US-2001/0032013).

Gumm discloses the invention substantially as claimed, but fails to disclose welding the secondary guidewire lumen to the balloon.

However, Marton teaches welding as a means to attach two components such a s tubes together.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the secondary guidewire lumen disclosed by Gumm to be attached by welding as taught by Marton. Such a modification would ensure the two components are

attached together more securely.

Claims 41, 42, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (US-20030055483) in view of Pinchuk et al. (US-2002/0107330).

Gumm discloses the invention substantially as disclosed above, but fails to disclose a polymer or therapeutic coating to the stentt.

However, Pinchuk teaches various therapeutic coatings (para.0005) and polymers (para.0016) as coatings on the stentt. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the stentt as disclosed by Gumm to include such coatings. Such a modification would enhance local drug delivery and reduce the systemic side effects associated with traditional oral drug delivery.

Regarding claims 51-55, Gumm in view of Pinchuk disclose the invention substantially as claimed. However, Gumm in view of Pinchuk is silent regarding the non-genetic therapeutic agent is selected from at least one member of the group consisting of heparin, or an anti-proliferative agent selected from enoxaprin, or an anti-inflammatory agents selected from prednisolone, or the non-genetic therapeutic agent is selected from paclitaxel or an anticoagulants selected from antithrombin compounds. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the non-genetic therapeutic agent is selected from at least one member of the group consisting of heparin, or an anti-proliferative agent selected from enoxaprin, or an anti-inflammatory agents selected from prednisolone, or the non-genetic therapeutic agent is selected from paclitaxel or an anticoagulants selected from antithrombin compounds, since it has been held to be within the

general skill of a worker in the art to select a known material on the basic of its suitability for the intended use. In re Leshin, 125 USPQ 416.

Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (US-20030055483) in view of Pinchuk et al. (US-2002/0107330).

Gumm discloses the invention substantially as disclosed above, but fails to disclose specific genetic coatings on a stentt or cells. However, Pinchuk teaches genetic therapeutic coatings (para.0077) such as antisense DNA and RNA or tumor necrosis factor or cells (para.0091) including stem cells. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the stentt as disclosed by Gumm to include a genetic coating as taught by Pinchuk. Such a modification would provide a means for gene delivery.

Response to Arguments

3. Applicant's arguments filed 08/29/2008 have been fully considered but they are not persuasive. In response to applicant's argument that Gumm does not suggest "a distal balloon waist being rotatable about a distal collar and a proximal balloon waist being rotatable about a proximal collar when the collars are in nonactivated states" (a functional limitation): It is noted that fig. 2 of Gumm can be clearly defined a distal balloon waist 32 is capable of rotating about a distal collar 26 and a proximal balloon waist 30 is capable of rotating bout a proximal collar when the collars 24, 26 are in nonactivated states. Therefore, it would have some sort of rotation with the balloon in Gumm when element 24 and 26 rotate. Thus, a reference needs not show the structure of the recitation in order to meet the claim language but rather the reference needs only be capable of being used with such structure.

Applicant states that Gumm fails to disclose the proximal and distal rotating member are not fixed to the catheter shaft. In fact, as seen in fig. 1 of Gumm, when viewed from a bird's eye point of view, it is possible for the proximal collar 24 fixed to the catheter 14 and the distal collar 26 fixed to the catheter shaft (see paragraph 40). Accordingly, the above noted reference is still considered to read on the claimed limitations of the claims noted.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ho Jackie can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

/Victor X Nguyen/
Examiner
Art Unit 3734

VN